FEB 0 1 2002

K014016

510(k) SUMMARY

1. Submitter Information:

Name:	Minntech Corporation
Address:	14605 28th Avenue North, Minneapolis, Minnesota 55447
Contact Person:	Mark Murphy
Date Prepared:	November 1, 1999

2. Device Name:

Proprietary name:	Minntech EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler
Common name:	Heater-Cooler
Classification name:	Temperature Controller, Cardiopulmonary Bypass per 21 CFR 870.4250

3. Predicate Device:

Cincinnati Sub-Zero Hemotherm Model 400 Cooler/Heater

4. Device Description:

The Minntech EnGUARD ™ CHC Dual Reservoir Cardioplegia Heater/Cooler is a portable heating and cooling circulation system with mechanical controls for delivery of warm or cool water to flow through type water pathway cardioplegia heat exchanger devices.

5. Intended Use:

The Minntech EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler is intended to be used as a self-contained temperature control device designed to deliver cooled or heated water to a cardioplegia heat exchanger in the cardiopulmonary bypass circuit.

6. Technological Characteristics:

A comparative summary of the EnGUARD™ CHC Heater/Cooler and predicate device is as follows:

Characteristic	EnGUAR™ CHC Dual Reservoir Cardioplegia Heater/Cooler	Cincinnati Sub-Zero Hemotherm Model 400 Cooler/Heater
Reservoirs/construction	Dual/plastic	Dual/plastic
Power requirements	100, 115. 240 VAC	100, 115. 240 VAC
Reservoir Capacity	Cool - 8 liters	Cool - 7.6 liters
	Heat - 6 liters	Heat - 5.7 liters
Fluid Heating Range	25°C to 42°C	25°C to 42°C
Fluid Cooling Range	Ice Water temperatures	32°C to 3°C
Connections	1/2" Hansen Fittings	1/2" Hansen Fittings
Hi Limit Temperature Control	43°C	44°C

7. Performance Testing:

The following performance testing was conducted to determine device effectiveness as a cardioplegia heater/cooler: Heating and Cooling Systems performance, Electrical Safety Testing and Water Bath Management.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 01 2002

Ms. Lynn Lueders
Director, Regulatory Affairs
Minntech® Corporation
14605 28th Ave. N.
Minneapolis, MN 55447

Re: K014016
Trade Name: EnGUARD™ CHC Dual reservoir Cardioplegia Heater/Cooler
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary bypass temperature controller.
Regulatory Class: Class II (two)
Product Code: DWC
Dated: November 27, 2001
Received: December 5, 2001

Dear Ms. Lueders:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): _____

Device Name: EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler

Indications for Use:

The Minntech Corporation's EnGUARD™ CHC Dual Reservoir Cardioplegia Heater/Cooler is intended to be used as a self-contained temperature control device to deliver cooled or heated water to a cardioplegia heat exchanger in the cardiopulmonary bypass circuit.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over-the Counter-use ___
(Per21 CFR 801.109) (Optional Format 1-1-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number k014016